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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,797	07/26/2002	Achim Gopferich	02592	1932
7590 07/10/2009 KENTON R. MULLINS STOUT, UXA, BUYAN & MULLINS, LLP 4 VENTURE SUITE 300 IRVINE, CA 92618				
EXAMINER				
SILVERMAN, ERIC E				
ART UNIT		PAPER NUMBER		
1618				
MAIL DATE		DELIVERY MODE		
07/10/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/019,797

**Applicant(s)**

GOPFERICH ET AL.

**Examiner**

ERIC E. SILVERMAN

**Art Unit**

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 5, 9-33, 36-38, 41-44, 60-63 and 66-70 is/are pending in the application.
- 4a) Of the above claim(s) 16-32, 60-63 and 66-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 9-15, 33, 36-38 and 41-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-22-09 has been entered.

### ***Election/Restrictions***

Newly submitted claims 67-70 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The new claims are related to the claims already examined as combination/subcombination.

Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed for patentability because even if the subcombination is unpatentable, the combination of the subcomponent bound to a surface might be patentable. The subcombination has separate utility such as a targeting moiety in a micelle or liposome.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in

accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. The inventions are distinct, each from the other because of the following reasons:

Accordingly, claims 67-70 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Pursuant to the amendment, claims 1-3, 5, 9-33, 36-38, 41-44, 60-63, and 66-70 are pending; claims 16-32, 60-63, and 66-70 are withdrawn; claims 1-3, 5, 9-15, 33, 36-38, and 41-44 are treated on the merits in this action.

The Examiner notes that claims 60-63 in the claim set submitted 6-15-09 have an improper status identifier. These claims should be identified as withdrawn. See the requirement for election/restriction mailed 12/17/2008, and the final office action mailed 4/22/2009 which identified these claims as being withdrawn. Applicants have not argued that the withdrawal of these claims is improper, nor did they traverse the restriction requirement. As Applicants' had ample opportunity to traverse (both in the response to the election and in the response to the 4/22/09 action), any traversal at this point would not be timely. Applicants' future communications should indicate claims 60-63 as being withdrawn.

***Claim Rejections - 35 USC § 102***

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 11, 14, 15 and 33 remain rejected under 35 U.S.C. 102(e) as being anticipated by US 6,254,890 to Hirosue.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5, 9-15, 33, 36-38 and 41-44 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hirosue in view of Domb.

***Response to Arguments***

Applicants' arguments were fully considered but are unpersuasive.

Applicants first argue that the disclosure in Hirosue does not provide enablement or written description for the claimed invention. In response to the argument that the disclosure does not provide enablement, a disclosure is enabled if a person of ordinary skill could make and use it without undue experimentation. Undue experimentation is determined in light of the factors enumerated in MPEP 2164.01. Applicants have not analyzed any of these factors, but instead have made a blanket conclusory statement that the prior art is not enabled. This argument therefore amounts to a mere allegation

of patentability, which cannot be persuasive. Furthermore, as demonstrated by the Gref article (cited on PTO 892), the synthesis of PEG-PLA was well known to the artisan by the time the Hirosue patent was filed.

In their argument that the prior art lacks written description, Applicants focus on the term PEG-PLA in the prior art, and allege that this term is ambiguous for two reasons. First, Applicants allege that it is not clear whether the PEG-PLA refers to linear or branched polymer (Applicants' also repeat this argument later when alleging that the reference does not read on claims requiring "substantially linear" polymers); second, Applicants allege that it is unclear whether PEG-PLA in Hirosue refers to a diblock. With regard to Applicants' first point, the Odian reference (cited on PTO 892) demonstrates that block copolymers are linear by definition. Therefore when reading about a block copolymer, the artisan assumes that the block copolymer is linear unless the literature specifies otherwise. Because patent specifications, such as Hirosue, are written for a skilled artisan and not for a layperson, they do not need to state what the artisan already knows. Here, the artisan knows that block copolymers are linear absent some statement to the contrary.

To support their contention that the term PEG-PLA might refer to a triblock rather than a diblock, Applicants' have sent an abstract that refers to PEG-PLA triblock copolymers. It is important to note that in this abstract, the PEG-PLA polymers are not called simply "PEG-PLA", but are specifically referred to as triblocks. There is a reason that the cited abstract specifically points out that the polymers referred to therein are triblocks. The Gref article (cited on PTO 892) at 1601 explains that there is an accepted

naming scheme for block copolymers of PEG with biodegradable polymers such as PLA, PCL, PGA, and the like. The accepted nomenclature is that the term PEG-R, where R is one of the abovementioned polymers, refers to the diblock of PEG and the polymer "R." This convention explains why Hirosue did not need to point out that the polymer is a diblock, whereas the abstract that Applicants' point to had to specifically point out that the abstract's polymer is a triblock. Hirosue was following the conventional naming system for diblocks, and did not need to explain that naming system because the artisan would already have been aware of it. Applicants' abstract, on the other hand, was deviating from the conventional naming system, and therefore had to explain at length the naming system being used therein.

Applicants' arguments with respect to the prior art's enablement and written description are presented from the point of view of a person unfamiliar with the art. This is not the appropriate viewpoint. Prior art is to be looked at through the eyes of a person of ordinary skill in the art. Such a skilled artisan would be familiar with the contents of Odian, an introductory textbook, and the Gref reference, a seminal paper in its field. The skilled artisan would therefore understand that the Examiner's interpretation of these references is correct, and that Applicants' allegations of ambiguity are based on ignorance, not on any defect in the references.

Applicants' next argue that Hirosue fails to disclose various aspects of the claims. Applicants' first such allegation is that Hirosue does not specify that the polymer is substantially linear. This argument addressed previously. Applicants' next allegation is that the Hirosue reference does not teach poly(ethylene glycol) amine. Applicants do,

however, specifically point to a teaching in Hirosue where N-hydroxysuccinimidyl esters are attached to the PEG portion of the copolymer. When Ny-hydroxysuccinimide is attached to the terminus of PEG, it is by way of the nitrogen atom and the PEG terminus is in the form of an amine. Thus, Hirosue implicitly teaches amine terminated PEG. Applicants' remarks about claims 62 and 67-70 are not germane because those claims are withdrawn.

Applicants make no new arguments with respect to the obviousness rejection, but merely allege that Domb fails to cure the supposed deficiencies in Hirosue. Because Hirosue is not deficient, this argument is not persuasive.

#### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/  
Primary Examiner, Art Unit 1618